UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** **ALL PLAINTIFFS LISTED IN EXHIBIT A TO PLAINTIFFS' NOTICE OF ADOPTION OF WAVE 1 MOTION**	**Master File No. 2:12-MD-02327** **MDL No. 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

ETHICON'S MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE CERTAIN OPINIONS AND TESTIMONY OF CHRISTINA PRAMUDJI, M.D.

INTRODUCTION

Plaintiffs filed a Notice of Adoption of their Motion to Exclude Certain Opinions and Testimony of Christina Pramudji, M.D. [Doc. No. 2035] and Supporting Memorandum [Doc. No. 2037] from Ethicon Wave 1. *See* Plaintiffs' Notice of Adoption, Doc. No. 2427. While Ethicon adopts and incorporates by reference its Response to that Motion ("Ethicon's Response") [Doc. No. 2153], given recent testimony from Dr. Pramudji and her updated Reports and reliance lists for Wave 2 cases, there is additional, relevant information to consider in addressing Dr. Pramudji's opinions on product warnings and that polypropylene mesh does not degrade in vivo.

Other than the supplementation of these two issues, Ethicon adopts and incorporates herein by reference its Wave 1 Response in relation to Dr. Pramudji [Doc. No. 2153].

BACKGROUND

Dr. Pramudji is a board-certified urologist with a sub-specialty in Pelvic Floor Medicine and Reconstructive Surgery. Ethicon's Response [Doc. No. 2153] at 1.[1] Her experience is vast, including "well over 1000" prolapse surgeries; "over 900 sling procedures" to treat SUI; 10 to 20 complete explants; and 50-60 revisions or partial removals. *Id*. She has also taught many surgeons on the use of mesh devices, has consulted with medical device companies in the development of slings to treat SUI, and has closely studied the medical literature and studies related to mesh, including Level 1 evidence such as Cochrane Review meta-analyses assessing thousands of patients, and numerous randomized controlled trials (RCTs), not to mention public statements by medical societies in the fields of urology. *Id*. at 1-2.

Plaintiffs seek to preclude Dr. Pramudji from testifying about the adequacy of the device IFUs, arguing that she is not an expert on regulations governing device manufacturers and is instead relying solely on her experience as a surgeon. And Plaintiffs attempt to preclude Dr. Pramudji from offering testimony that polypropylene mesh products do not degrade in the human body. None of Plaintiffs' arguments has merit, and their Motion should be denied.

A. Dr. Pramudji is qualified to testify about the general knowledge of pelvic floor surgeons and the impact of such knowledge on Ethicon's Warnings and IFUs.

"[D]octors are fully qualified to opine on the medical facts and science regarding the risks and benefits of drugs and to compare that knowledge with what was provided in the text of labeling and warnings." *Winebarger v. Boston Scientific Corp.*, 2015 WL 1887222, at *5 (S.D. W. Va. Apr. 24, 2015). Dr. Pramudji's testimony should be considered in light of the controlling legal principle that a device manufacturer's duty to warn of adverse events does not include a

[1] Ethicon will not restate the entirety of Dr. Pramudji's qualifications here, but refers the Court to its Response, Doc. No. 2153, at 1-2.

duty to warn of risks commonly known to the surgeons who use the device. Even the FDA device regulations recognize the importance of a physician's knowledge base by allowing certain information to be omitted from labeling:

> if, but only if, the article is a device for which directions, hazards, warnings and other information are *commonly known to practitioners* licensed by law to use the device.

21 C.F.R. §801.109(c) (emphasis added).

As a result, Dr. Pramudji's testimony concerning what a trained pelvic floor surgeon would know to be the risks associated with pelvic floor surgeries, including surgery using mesh, is a key inquiry here, and she is undoubtedly qualified to render opinions on this topic. So, too, Dr. Pramudji's analysis of the pertinent medical literature supports her conclusions that numerous risks attendant to performing the surgery and using the device would be commonly known to these practitioners (surgeons like herself) licensed to implant the device and that certain risks espoused by Plaintiffs' experts are unverified and therefore need not be included in the IFU. *See, infra*, regarding Dr. Pramudji's opinions on degradation.

This makes sense in light of the fact that the contents of the IFUs must be assessed in terms of both what the class of surgeons who are to use the devices know and how their training would impact their review of the IFUs. *See, e.g.*, Ex. C to Ethicon's Response, TVT IFU at 28 ("Users should be familiar with surgical techniques for bladder neck suspension and should be adequately trained in implanting the TVT system." And, that the IFU "is not a comprehensive reference to surgical technique for correcting SUI (Stress Urinary Incontinence)."); Ex. D to Response, TVT-O IFU at 5 (device to be used "only by physicians trained in the surgical treatment of stress urinary incontinence and specifically in implanting the Gynecare TVT Obturator device."); Ex. A, Prolift IFU at 2 ("Training on the use of the GYNECARE

PROLIFT* Pelvic Floor Repair Systems is recommended and available") and at 6 ("WARNINGS AND PRECAUTIONS: Users should be familiar with surgical procedures and techniques involving pelvic floor repair and nonabsorbable meshes before employing the GYNECARE PROLIFT Pelvic Floor Repair Systems.")).

Dr. Pramudji has recently expounded on her experience in training other physicians in the use of mesh devices, including evaluating the risks to determine appropriate patients and how her experience as a pelvic surgeon plays into that. For example, in *Shelton v. Ethicon, Inc.*, No. 2:12-cv-01707, upon questioning by Plaintiff's counsel, Dr. Pramudji testified that she taught other physicians about Ethicon mesh products, how to implant them, and how to identify a proper patient for treatment using mesh. Ex. B, Pramudji (*Shelton* 7/12/16) Dep. at 54-55. She highlighted that her experience and professional education, in combination with reading medical literature over her decades of practice, has informed her opinion regarding the risks and complications of pelvic floor surgery and pelvic floor surgery using mesh. *Id*. at 68-70. And she also testified that she knows what risks and complications are known to pelvic surgeons, the intended product users, not only through her experience, but also through a thorough review of the literature over many years. *Id*. at 68-70 (citing Iglesia, C.B., *The Use of Mesh in Gynecologic Surgery*, Int. Urogynecol J (1997) 8:105-115, which was a literature review from 1950 to 1997 published in the International Urogynecology Journal, that reported risks to practitioners like Dr. Pramudji).

Dr. Pramudji edified her opinions concerning the knowledge base of pelvic surgeons and what pelvic surgeons fundamentally and commonly know based upon experience in that surgical field. "A fundamental part of training to pelvic floor surgeons" is that surgery in the pelvic area can cause certain complications that are customarily raised by Plaintiffs in this litigation,

including scarring in the vagina and inflammation in the vaginal wall, which can result in dyspareunia. Ex. C, Pramudji (*Bihlmeyer v. Ethicon, Inc.*, No. 2:12-cv-02159) (6/9/16) Dep. at 95. She explained that medical studies dating back to 1961 tracked the connection between pelvic floor surgery and dyspareunia. *Id*. at 95-96. For more than 50 years, pelvic surgeons in the field have understood the well-accepted risks of pelvic floor surgery to include scarring and tenderness, potential narrowing of the introitus and vagina and dyspareunia. *Id*. at 96. This is consistent with her General Expert Reports. *See*, Ex. C to Plaintiff's Motion [Doc. No. 2035], Pramudji Gynemesh/Prolift/Prosima General Report, at 16 ("Pain, pelvic pain and dyspareunia can occur with all POP surgeries.") (citing ACOG 2011 Committee Opinion 513; AUA 2011 Position Statement on the use of vaginal mesh for the repair of pelvic organ prolapse; Lowman, J., *Does the Prolift system cause dyspareunia?* Am J Obstet Gynecol 2008, 199:707.e1-707.e6; Francis, WJA, Jeffcoate, TNA, *Dyspareunia following vaginal operations*, J Obstet Gynaecol Br Commonwealth, 1961, LXVIII(1):1-10 (discussing complications following colporrhaphy prolapse repair)); and at 15 ("All POP and vaginal surgeries have potential risks.") (citing Ex. D, Diwadkar, *Complication and reoperation rates after apical vaginal prolapse surgical repair: a systematic review*, Obstet Gynecol 2009, 113:367–73 (published in the official publication of the American College of Obstetricians and Gynecologists, and reviewing literature from 1985 to January 2008 using PubMed, Cochrane databases, and the Database of Abstracts of Reviews and Effects and reporting numerous risks and complications to practitioners of pelvic floor surgery); *see also* Diwadkar, at Table 2:

Table 2. Weighted Averages and Confidence Intervals of Complications, Dindo Grades, Prolapse Reoperation Rates, and Total Reoperation Rates

	Traditional Vaginal Repair*	Sacral Colpopexy	Mesh Kits
Number of studies†	48	52	24
Number of patients	7,827	5,639	3,425
Mean follow-up (mo±SD)	32.6±19.8	26.5±20.1	17.1±13.8
Dindo grade I	6.2 (5.7–6.7), 0–52.8	5.5 (4.9–6.1), 0–52.2	3.9 (3.3–4.6), 0–23.1
Dindo grade II	6.9 (6.4–7.6), 0–34.7	5.8 (5.2–6.4), 0–25.9	2.2 (1.7–2.7), 0–14.8
Dindo grade IIIa	0.2 (0.1–0.4), 0–2.1	1.0 (0.7–1.2), 0–8.3	1.3 (0.9–1.6), 0–12.7
Dindo grade IIIb	1.9 (1.7–2.3), 0–12.0	4.8 (4.2–5.4), 0–28.2	7.2 (6.3–8.0), 0–21.2
Dindo grade IVa, b	0.1 (0–0.1), 0–1.0	0.0 (0–0.07), 0.0	0.0 (0–0.1), 0.0
Dindo grade V	0.1 (0–0.1), 0–0.7	0.0 (0–0.07), 0.0	0.0 (0–0.1), 0.0
Mesh erosion or infection	0.5 (0.3–0.6), 0–20.0	2.2 (1.8–2.6), 0–28.2	5.8 (5–6.6), 0–21.2
Visceral injury‡	1.0 (0.8–1.3), 0–5.9	1.7 (1.3–2.0), 0–10.7	1.1 (0.7–1.4), 0–5.0
Cystotomy	0.4 (0.2–0.5), 0–5.9	1.0 (0.8–1.3), 0–10.7	0.7 (0.4–1.0), 0–4.3
Ureteral injury	0.3 (0.2–0.4), 0–3.5	0.2 (0.1–0.3), 0–1.6	0.1 (0–0.1), 0–1.0
Bowel injury	0.4 (0.3–0.5), 0–3.1	0.5 (0.3–0.7), 0–3.6	0.3 (0.1–0.5), 0–5.0
Pain§	1.6 (1.3–1.9), 0–38.9	2.3 (1.9–2.6), 0–25.0	2.5 (2.0–3.0), 0–23.1
Buttock pain	1.0 (0.8–1.3), 0–52.8	0.0 (0–0.07), 0–5.9	0.4 (0.2–0.7), 0–8.3
Dyspareunia	1.5 (1.2–1.8), 0–38.9	1.5 (1.1–1.8), 0–22.8	2.2 (1.7–2.7), 0–23.1
Fistula	0.1 (0–0.1), 0–1.5	0.0 (0–0.07), 0–0.8	0.2 (0.1–0.4), 0–4.2
Hemorrhage or hematoma	2.8 (2.5–3.3), 0–19.6	1.6 (1.3–1.9), 0–11.5	1.1 (0.7–1.4), 0–3.0
Wound complications‖	0.5 (0.4–0.7), 0–10.8	1.5 (1.2–1.8), 0–16.8	0.2 (0–0.3), 0–7.5
Pelvic abscess	0.2 (0.1–0.3), 0–1.4	0.1 (0–0.2), 0–3.2	0.1 (0–0.2), 0–3.3
Lower extremity neuropathy	0.4 (0.3–0.6), 0–7.5	0.2 (0.1–0.3), 0–0.5	0.0 (0–0.1), 0.0
Urinary tract infection	3.5 (3.1–3.9), 0–34.8	2.1 (1.8–2.5), 0–25.9	0.8 (0.5–1.2), 0–14.8
Pulmonary embolism or deep vein thrombosis	0.1 (0.1–0.2), 0–2.2	0.3 (0.1–0.4), 0–3.2	0.0 (0–0.1), 0–1.4
Pulmonary complications	0.5 (0.4–0.7), 0–14.0	0.1 (0.1–0.4), 0–0.7	0.0 (0–0.1), 0.0
Cardiac complications	0.2 (0.1–0.3), 0–2.2	0.2 (0.1–0.3), 0–3.3	0.0 (0–0.1), 0.0
Total complication rate	15.3 (14.7–16.3), 0–52.8	17.1 (16.1–18.1), 0–52.2	14.5 (13.3–15.7), 0–23.1
Reoperation for prolapse recurrence	3.9 (3.5–4.4), 0–29.1	2.3 (1.9–2.7), 0–31.3	1.3 (1.0–1.7), 0–16.0
Total reoperation rate¶	5.8 (5.3–6.3), 0–29.2	7.1 (6.4–7.8), 0–26.2	8.5 (7.6–9.4), 0–30.0

SD, standard deviation.
Data are % (95% confidence interval), range unless otherwise specified.
* Includes sacrospinous ligament suspension, uterosacral ligament suspension, iliococcygeus muscle suspension, and McCall's culdoplasty.
† Ten studies included multiple cohorts from different procedure groups.
‡ Includes cystotomy, ureteral injury, and bowel injury.
§ Includes buttock pain, dyspareunia, and unspecified pain.
‖ Includes wound infections, vaginal cuff infections, and vaginal and abdominal wound dehiscences.
¶ Includes reoperations for complications (Dindo IIIb) and prolapse recurrence.

See also Ex. B to Plaintiffs' Motion [Doc. 2035], Pramudji TVT/TVTO General Report at 4 ("Potential risks of operating in this area are well described to surgeons during training, in medical textbooks, and in the medical literature, and are well known risks" and generally discussing risks set forth in the medical literature).

All of this supports her qualifications to testify about the general knowledge of pelvic floor surgeons and why, given that general knowledge base, warnings that Plaintiffs insist should have been included in the product warnings were simply not necessary in light of the knowledge of the intended user of the product.

In addition, Dr. Pramudji's experience qualifies her to testify concerning the common interpretation of the risks set forth in the IFU to those trained in such surgeries. *See, e.g.*, Ex. E, Pramudji (*Wilson v. Ethicon, Inc.*, No. 2:12-cv-02099) (7/6/16) Dep. at 77-83 (discussing that risks known to pelvic surgeons would impact the surgeon's interpretation of the language in the product warnings).

Given that the product IFUs note that only surgeons trained in pelvic floor surgery should use Ethicon pelvic mesh products, Defendants' Response Memorandum [Doc. No. 2153] at 5-6, what a trained physician would know is critical to the analysis of the adequacy of the warning. Dr. Pramudji is well-versed by her education, training and experience – including her experience training other surgeons – to discuss what risks would be known generally to the class of users of such mesh devices. She is further qualified by her work as a preceptor and Ethicon trainer to discuss what training Ethicon provided, including the format of the training as well as its content. Ex. C, Pramudji (*Bihlmeyer*) Dep. at 96-98; Ex. B, Pramudji (*Shelton*) Dep. at 54-56.

Dr. Pramudji is not opining that certain risks need not be included in the IFU just because she has not observed them in her own practice. Instead, her testimony rests not only her own experience but on her historical review of the medical literature as well as her experience in teaching medical professionals and the statement of the professionals themselves through their professional associations. Such opinions are fully supported by her years of education, training and experience: qualifications that Plaintiffs do not challenge. *See* Plaintiffs' Reply Memorandum in Support of Motion to Exclude Certain Opinions of Christina Pramudji, M.D. [Doc. No. 2236] at 1 ("Plaintiffs' Motion is not based on lack of qualifications…"). Yet qualifications are at the heart of Dr. Pramudji's opinion that, given the knowledge of pelvic floor surgeons, the product warnings were adequate.

This Court's rulings in *Tyree* and *Bellew* are distinguishable. *See Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 584 (S.D. W. Va. 2014); *Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473, Memorandum Opinion and Order (Daubert Motions), Doc. 265 at 33 (S.D. W. Va. Nov. 20, 2014). While a single physician's experience may not be sufficient, it is sound methodology to rely upon a large pool of scientific literature and studies, combined with the

clinical experience and evaluation of many physicians and medical organizations, to support a conclusion that certain risks do not occur and therefore need not be included in the IFU, as Dr. Pramudji has done here. Indeed, when Plaintiffs' experts have concluded that risks do occur based on such support, they are allowed to testify that the risk should have been included in the mesh warnings. *Tyree*, 54 F. Supp. 3d at 561. In *Tyree*, Dr. Blaivas was permitted to testify as to whether any "inaccuracies or omissions could either deprive a reader or mislead a reader of what the risks and benefits" of the product was. *Id*. It stands to reason that an expert employing this same, or better, methodology, while reaching a different conclusion concerning the impact of a claimed omission on a trained surgeon, has also provided admissible testimony. That Plaintiffs may disagree with Dr. Pramudji's conclusion can be addressed on cross-examination.

Plaintiffs argue that Dr. Pramudji does not support her opinion on what pelvic floor surgeons know with any specific study or research, which is a far too restrictive reading of *Daubert*. Plaintiffs' Reply in Further Support of their Motion to Exclude Certain Opinions and Testimony of Christina Pramudji, MD [Doc. No. 2236] at 2-4. Yet they have likewise failed to identify any study that challenges Dr. Pramudji's assessment of what risks or complications are so obvious or so common to pelvic floor surgery that any surgeon attempting to perform surgery should know it. Some risks and complications are just so well understood that there is no reason to conduct a study to quantify them. In fact, this Court recognized that expert opinion based on clinical practice is "obviously … not subject to testing or peer-review." *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 727 (S.D. W. Va. 2014). Nor does *Daubert* require such testing when an expert is relying upon her education, training and experience to form her opinions. *Id*. at 726. And Plaintiffs do not address the fact that Dr. Pramudji bases her opinions on her extensive review of the medical literature as set forth in her General Reports, which informs practitioners

who would use the device, as well as risks commonly taught in the training of the pelvic surgeon, which she is certainly qualified to give.

And just because some hypothetical physicians may overestimate their abilities to perform surgeries that they lack the training to perform does not render inadmissible generalizations about what someone who *is* qualified to perform such surgeries would know. *See* Plaintiffs' Reply [Doc. No. 2236] at 3-4. Such generalizations are not only proper but expressly approved of by the FDA regulations applying to warnings. Those regulations provide that information may be omitted from labeling "if, but only if, the article is a device for which directions, hazards, warnings and other information are **commonly known** to practitioners licensed by law to use the device." 21 C.F.R. §801.109(c) (emphasis added). Thus, the regulations themselves contemplate that some generalization of knowledge of the intended users is properly considered. Other than through testimony from such intended users, it would not be possible to meet this standard.

Given the established relevance of the knowledge of pelvic floor surgeons generally, and given Dr. Pramudji's unassailable education, training and experience as a pelvic floor surgeon, her extensive review of the medical literature which outlines risks that would inform the intended user, her review of the devices' professional education materials and her teaching to and interaction with other intended users concerning risks and the IFU, her testimony regarding such general knowledge and how such general knowledge impacts the interpretation of the product warnings by the intended user is proper.

B. Dr. Pramudji's opinion that polypropylene mesh does not degrade in vivo is further supported by recent medical literature.

This Court has previously ruled that Dr. Pramudji can testify about whether she has observed mesh degradation in her clinical practice. *Huskey v. Ethicon, Inc.,* 29 F. Supp. 3d 691,

726 (S.D. W. Va. 2014). Such opinions are proper given her considerable experience and her review of mesh images received from pathologists. *Id*.

In *Huskey*, Ethicon agreed that Dr. Pramudji would not testify regarding the chemical process of degradation of polypropylene. The same holds true here. However, Dr. Pramudji is qualified to opine beyond just the fact that she has not seen degradation in her clinical practice. She can also testify that the medical literature does not support the conclusion that polypropylene mesh degrades in vivo. *See, e.g.*, Ex. F, Pramudji Supplemental Reliance list for Wave 2 (*Shelton*).

Dr. Pramudji has reviewed extensive medical literature on this subject and routinely keeps up to date on such literature. *See* General Reports, Exs. B and C to Plaintiffs' Motion [Doc. No. 2035]; Reliance List, Ex. B to Ethicon's Response [Doc. No. 2153]; *see, e.g.*, Ex. F, Supplemental Reliance List for Wave 2 (*Shelton*). For example, in her TVT General Report she outlines that "Degradation of the mesh has not been demonstrated by reliable data. While there have been reports of 'surface cracking' such as that described in the Clave 2010 paper, the authors there confirm that the phenomenon which was only observable in a minority of specimens could not be demonstrated on analytical chemical testing." Ex. B to Plaintiffs' Motion [Doc. No. 2035] at 62-63. "Moreover, the methodology of the paper was flawed and unable to rule out that the surface cracking was not biofilm. The data do not support that any surface cracking causes clinical symptoms…. Prospective studies have followed patients with implanted with TVT and TVT-O for 5-17 years and show excellent durability and safety with the use of the macroporous Prolene polypropylene sling. (citations omitted). Numerous data cited in my report show that the macroporous Prolene polypropylene tape is well tolerated and provides lasting efficacy for SUI." *Id*. at 63-64. After citing a host of medical literature and studies analyzing

the lack of degradation, Dr. Pramujdi properly opines that "[t]hese data are inconsistent with Plaintiff's experts' theories." *Id*. at 65. *See also* Ex. C to Plaintiffs' Motion [Doc. No. 2035] at 3 ("The data in women does not support that Gynemesh PS degrades, as reoperation rates for recurrence are low, cure rates and satisfaction is high, and complication rates are not consistent with degradation or that if it did degrade, it would have a clinically significant effect") and at 15-35, 40-46 (regarding the data which she has reviewed and which does not support Plaintiffs' degradation theory). As she testified in a recent deposition:

> Q. You were asked a question about whether all of the general materials in your prior general report are the entire scope of your general opinions.
>
> Do you recall a question somewhat along those lines?
>
> A. Yes.
>
> ***
>
> Q. Doctor: Have you, since the time of your most recent general Gynemesh Prolift report, continued to review the literature with regard to those products?
>
> A. Yes.
>
> Q. And have you, in prior depositions, noted the additional materials that you have reviewed that don't change your opinion but are just further supportive of your opinions?
>
> A. Yes.
>
> ***
>
> Q. [Such as] The paper to be presented at IUGA on the lack of support for a degradation theory showing that the correct material is instead a biologic proteinaceous material?
>
> A. Yes.

Ex. B, Pramudji (7/12/16) Dep. (*Shelton*) at 61-62. As noted on Dr. Pramudji's updated reliance list and referenced in her above testimony, she has reviewed and considered a recent study that

shows that the substance on mesh explants that Plaintiffs' experts claim is degrading polypropylene is instead a protein layer produced by the human body. Ex. F, Supplemental Reliance list for Wave 2 (*Shelton*) at 28 (citing Ex. G, Ong, Thames, et.al, *The Myth: In Vivo Degradation of Polypropylene Meshes*, Int Urogynecol J (2016) 27 (Suppl 1):S37-38). This study specifically examined the flaking particles on explanted mesh, including cracked and uncracked regions, through numerous methods and found that the meshes did not undergo degradation; instead the particles and cracked layer were actually an adsorbed protein layer, i.e., a natural and well-known reaction by the human body to the implantation of a foreign device. *Id*. This study fully supports Dr. Pramudji's testimony that in vivo degradation of polypropylene mesh is not established in either her clinical experience or in the medical literature. Since such literature is the kind of information relied upon by clinicians like Dr. Pramudji in their medical practice, she is qualified to offer an opinion that not only has she never seen degradation of polypropylene mesh in her personal experience, but that the medical literature does not support such a finding.

In *Huskey*, this Court permitted Dr. Harry Johnson to testify to just that. *Huskey*, 29 F. Supp. 3d at 733-34. The basis for his opinion was Dr. Johnson's clinical experience and review of medical literature on the subject. *Id*. So, too, Dr. Pramudji should be permitted to testify that medical literature does not support that polypropylene mesh degrades.

As in *Trevino v. Boston Scientific Corp.*, 2016 WL 2939521, at *7 (S.D. W. Va. Apr. 28, 2016), Dr. Pramudji "considered and analyzed multiple scientific articles" and "drew on [her] clinical experience" to reach her opinion that polypropylene does not degrade. This Court found that this constitutes a "reliable, scientific methodology." *Id*. Thus, Dr. Pramudji is qualified to

opine on the lack of evidence that polypropylene degrades from both her clinical experience and from the medical literature, and her opinion meets *Daubert* criteria. *Id*.

CONCLUSION

For the reasons set forth above, and all reasons set forth in Ethicon's Response to Plaintiffs' Motion to Exclude Certain Opinions of Dr. Pramudji [Doc. No. 2153], the Court should deny Plaintiffs' Motion.

This the 8th day of August, 2016.

Respectfully submitted,

ETHICON, INC. AND
JOHNSON & JOHNSON

/s/ David B. Thomas
David B. Thomas (W. Va. Bar No. 3731)
Thomas Combs & Spann, PLLC
300 Summers Street, Suite 1380
P.O. Box 3824
Charleston, WV 23558-3824
(304) 414-1800

/s/ Christy D. Jones
Christy D. Jones
Butler Snow LLP
1020 Highland Colony Parkway
Suite 1400 (39157)
P.O. Box 6010
Ridgeland, MS 39158-6010
(601) 985-4523

CERTIFICATE OF SERVICE

I certify that on August 8, 2016, I electronically filed this document with the Clerk of the Court using the CM/ECF system which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ Christy D. Jones
Christy D. Jones